Special 510(k) Device Modification
PREMARKET NOTIFICATION
SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST™ System with FlexShaft 2

In Accordance with 21 CFR section 807.92 Power Medical Interventions, Inc., is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
215-862-4450 Ph
215-862-1009 Fax

Applicant: Barbara J. Whitman

Date of Notification: April 17, 2002

2) Name of Device:

Trade Name: SurgASSIST™ System
With FlexShaft 2

Common Name: FlexShaft 2, Flexible Shaft

Classification Name: Staple, Implantable, GDW; Stapler, GAG

3) Predicate Devices:

a) SurgASSIST™ System with Circular Stapler Disposable Loading Unit with Titanium Implantable Staple, Power Medical Interventions, Inc., K003277.

b) SurgASSIST™ System with Right Angle Linear Cutter Digital Loading Unit™, Power Medical Interventions, Inc., K012809.

4) Device Description:

The FlexShaft 2 resembles a colonoscope and provides the mechanical and electrical interface between the PC and the DLU. The FlexShaft 2 has a rigid mechanical assembly at the proximal end that provides the mechanical interface between the FlexShaft 2 and PC. The remainder of the FlexShaft 2 is flexible throughout its length and incorporates an articulation section near the distal end that allows for remote positioning of the DLU. The distal tip of the FlexShaft 2 has features that allow for the attachment and removal of various configurations of a DLU.

The FlexShaft 2 contains two drive shafts that couple two motors in the PC to the two inputs of a DLU. Rotary motion provided by the motors located in the PC is delivered to the DLU through these drive shafts for various purposes such as clamping tissue or forming staples.

The distal assembly of the FlexShaft 2 contains a printed circuit board that has two pairs of hall-effect transistors mounted. Each pair of hall-effect transistors is arranged for quadrature output to enable tracking of the rotation of the two drive shafts at the distal end. This tracking provides the signal to the PC to insure that the appropriate number of shaft revolutions is delivered to the DLU.

Internal to the FlexShaft 2 are four braided (steering) cables. The purpose of these cables is to provide the means for articulating the steering section of the FlexShaft 2. Articulation is achieved when tension is applied to the cable or cables located in the desired articulation direction. Rotary motion, provided by motors in the PC, is translated into linear "cable pull" motion through a pairs of bevel gears that are coupled to capstans.

Since the DLU contains an electronic "chip" carrying its identification and usage status, it must be able to communicate with the micro controller within the PC. The FlexShaft 2 incorporates two electrical contacts that mate with corresponding contacts on the DLU when the DLU is attached to the FlexShaft 2.

Internal to the FlexShaft 2 is a usage counter. The purpose of this counter is to allow the storage of information relating to the number of DLU's fired and the number of FlexShaft 2 attachments to the PC. Each memory module has a unique serial number that will be used for FlexShaft 2 identification.

5) Indications For Use - The FlexShaft 2 will have identical Indications For Use as the predicate device.

The SurgASSIST™ System with Circular Stapler DLU, has applications throughout the alimentary tract for end-to-end and side-to-side anastomosis.

The SurgASSIST™ System with Right Angle Linear Cutter Digital Loading Unit™ has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomosis.

6) Comparison to Predicate Devices

The following table compares the subject FlexShaft 2 device to the previously cleared predicate FlexShaft device:

FlexShaft Product Features Comparison Chart

Features & Description	SurgASSIST™ w/ FlexShaft 2 (FS214)	Predicate SurgASSIST™ w/ the original FlexShaft (FS14)
Name	SurgASSIST™ System with FlexShaft 2	SurgASSIST System with FlexShaft component
Manufacturer of Record	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.
Contract Manufacturer	Gore & Associates, Inc. Newark, DE	Design Standards Corporation Charlestown, NH
510(k) Clearance Numbers	Subject of this Notification	K003277
Product Codes	FS214	FS14
Intended use	Applications throughout the alimentary tract for end to end, end to side, and side to side anastomosis. Also, applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.	Applications throughout the alimentary tract for end to end, end to side, and side to side anastomosis
FDA Class (System)	II	II
Physical Characteristics	----------	----------

FlexShaft Product Features Comparison Chart - continued from previous page

Length of FlexShaft	2 meters ± 3cm	2 meters ± 3cm
Length of Articulation Section	10cm ± 2cm	10cm ± 2cm
Diameter of Articulation Section	15mm ± .25mm	15mm ± .25mm
Articulated tip Steering	4 Braided Cables	4 Braided Cables
Diameter of flexible non-articulation section	13.5mm ± .25mm	13.5mm ± .25mm
Weight	2.15 lbs ± .25 lbs	2.15 lbs ± .25 lbs
Color - Articulation Sheath	Black	Black
Color - Insertion Tube	Black	Black
Color - Proximal End Receptacle	Black	Black
Color - Distal End Receptacle	Stainless Steel	Stainless Steel
Color - Lettering	White	White
Internal Power	None	None
Electrical Contacts	2	2
Software Containing	Yes - Usage counter memory module relating to the # of DLUs fired.	No
How Supplied	Non-Sterile, plastic wrapped in single unit corrugated box	Non-Sterile, plastic wrapped in single unit corrugated box
Recommended Method of Sterilization	Steam (Flash) Sterilization; ETO; Cold liquid sterilant (FDA cleared); and Gas plasma sterilization	ETO; Cold liquid sterliant (FDA cleared)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2002

Ms. Barbara J. Whitman
Regulatory Affairs Specialist
Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938

Re: K021249
Trade/Device Name: SurgASSIST™ System with FlexShaft 2
Regulation Number: 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: April 18, 2002
Received: April 19, 2002

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021249

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) No. K 021249

Device Name: *SurgASSIST™ System with FlexShaft 2*

INDICATIONS FOR USE: (Note: The intended use for this product modification will be substantially identical to that of Power Medical Interventions, Inc. immediate predicate 510(k) Notification's, K003277 & K012809).

The SurgASSIST™ System with Circular Stapler Digital Loading Unit™ (DLU), has applications throughout the alimentary tract for end-to-end and side-to-side anastomosis.

The SurgASSIST™ System with Right Angle Linear Cutter DLU has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomosis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X OR Over-The-Counter Use _____
Per 21CFR §801.109

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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510(k) Number K021249